UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,415	01/04/2002	David Baltimore	APBI-P04-035	7747

28120 7590 03/28/2006

FISH & NEAVE IP GROUP
ROPES & GRAY LLP
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER	
GUZO, DAVID	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,415	BALTIMORE ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-88* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to isolated nuclear proteins which bind to transcriptional regulatory DNA elements of immunoglobulin genes, classified in class 530, subclass 350.

II. Claims 5-6, drawn to isolated nuclear proteins which bind to DNA sequences upstream of both mouse heavy and kappa light chain gene promoters and binds to mouse heavy chain gene enhancer, classified in class 530, subclass 350.

III. Claims 7-9, 49 drawn to isolated nucleic acids encoding nuclear proteins which bind to transcriptional regulatory DNA elements of immunoglobulin genes, classified in class 536, subclass 23.1.

IV. Claim 10, drawn to an isolated DNA encoding a structural gene for a nuclear protein which binds in a sequence specific manner to the kappa enhancer, classified in class 536, subclass 23.5.

V. Claims 11-12, drawn to isolated DNA which encodes a nuclear protein which binds to DNAs in the upstream region of both mouse heavy and kappa light chain gene promoters and binds to DNA sequences of mouse heavy chain gene enhancer, classified in class 536, subclass 23.1.

VI. Claim 13, drawn to a cloned DNA sequence which encodes a protein which binds to TGGGGATTCCCCA and hybridizes to a 10kb RNA

transcript form both B and non-B human cells, classified in class 536, subclass 23.5.

VII. Claims 14-16, drawn to an assay for detection of binding of cellular nuclear protein to DNA, classified in class 435, subclass 6.

VIII. Claims 17-23, drawn to a method of enhancing the transcription of a gene of interest whose transcription is regulated by a regulatory factor which binds DNA in the vicinity of a gene, classified in class 435, subclass 455.

IX. Claims 24-27, drawn to lymphoid cells, classified in class 435, subclass 325.

X. Claim 28, drawn to a method of screening for the expression of a sequence-specific binding protein by a recombinant expression vector, classified in class 435, subclass 6.

XI. Claims 29-35, drawn to a method of identifying recombinant expression vectors, classified in class 435, subclass 320.1.

XII. Claims 36-41, drawn to DNA probes and methods of detecting DNA or RNA, classified in class 536, subclass 24.3.

XIII. Claims 42-44, drawn to polyclonal or monoclonal antibodies and an immunoassay, classified in class 530, subclass 387.1.

XIV. Claim 45, drawn to phage lambda h3, ATCC 67629, classified in class 435, subclass 320.1.

XV. Claim 46, drawn to phage OCT-2, ATCC 67630, classified in class 435, subclass 320.1.

XVI. Claim 47, drawn to a method of identifying an agonist or antagonist of gene transcription, classified in class 435, subclass 7.1.

XVII. Claims 48, 87-88, drawn to an agonist or antagonist of nuclear proteins which bind to transcriptional regulatory DNA elements of immunoglobulin genes, classified in class 530, subclass 324.

XVIII. Claims 50-53, drawn to a method of specifically stimulating gene transcription in a cell, classified in class 435, subclass 455.

XIX. Claims 54-56, drawn to a method of inducing expression of a gene, classified in class 435, subclass 320.1.

XX. Claims 57-61, drawn to a method of altering expression in a cell of a gene whose transcriptional activity is altered by binding of NK-κB to the enhancer of said gene, classified in class 435, subclass 7.1.

XXI. Claims 62-63, drawn to a method of controlling expression of HIV DNA in a host cell, classified in class 435, subclass 5.

XXII. Claim 64, drawn to an isolated NF-κB - IκB complex, classified in class 530, subclass 350.

XXIII. Claim 65, drawn to isolated DNA encoding NF-κB - IκB complex, classified in class 536, subclass 23.1.

XXIV. Claims 66-73, drawn to a method of regulating NF-κB mediated gene expression in a cell, classified in class 435, subclass 7.1.

XXV. Claims 74-77, drawn to a method of positively regulating the expression of a gene in a cell, classified in class 435, subclass 455.

XXVI. Claims 78-83, drawn to a method of negatively regulating the expression of a gene in a cell, classified in class 435, subclass 6.

XXVII. Claims 84-85, drawn to a method of modifying the expression of at least one gene in a cell, the gene having a NK-κB binding site, classified in class 435, subclass 455.

XXVIII. Claim 86, drawn to isolated or recombinant IκB, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, XIII, XXII, XXVIII and III, IV, V, VI, XII and XXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions I, II, XIII, XXII, XXVIII relate to proteins and the inventions III, IV, V, VI, XII and XXIII all relate to nucleic acids. Proteins are functionally, biochemically and structurally distinct from nucleic acids and are capable of supporting separate patents. A search of one would not be co-extensive with a search of the others and hence would be burdensome.

Inventions VII, VIII, X, XI, XVI, XVIII-XXI, XIV-XVI and XVII are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP §806.05(j). In the instant case, the different processes utilize different process steps or are directed

to unrelated outcomes. For example, the invention of Group VII is directed to assaying for detection of binding of cellular nuclear protein to DNA, said method comprising preparing an incubation mixture comprising radiolabeled DNA fragments, an alternating copolymer duplex of poly (dI-dc)-poly (dI-dc), etc. incubating the mixture to allow for formation of protein-DNA complexes and resolving complexed DNA from free DNA, etc. while the invention of Group VIII involves a method of enhancing the transcription of a gene whose transcription is regulated by a regulatory factor which binds DNA in the vicinity of the gene wherein said method involves completely unrelated method steps.

Inventions IX, XIV, XV and I, II, XIII, XXII, XXVIII, III, IV, V, VI, XII and XXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions involving the lymphoid cells and phage of Groups IX, XIV, XV are distinct from the other proteins and nucleic acids of Groups I, II, XIII, XXII, XXVIII, III, IV, V, VI, XII and XXIII in that the cells and phage are distinct compositions with unique properties. A search of one would not be co-extensive with a search of the others and hence would be burdensome.

Inventions IX, XIV, XV and VII, VIII, X-XII, XVI, XVIII, XIX-XXI, XXIV-XXVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions involving Groups IX, XIV, XV (lymphoid cells, recombinant phage) are unrelated to the

method Groups VII, VIII, X-XII, XVI, XVIII, XIX-XXI, XXIV-XXVIII because none of the method Groups require the specifics of the compositions of Groups IX, XIV, XV and said compositions could be used in alternative methods of using.

Inventions I-VI, XII, XIII, XXII, XXIII, XXVIII and VII, VIII, X-XII, XVI, XVIII, XIX-XXI, XXIV-XXVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case each of the product inventions (Groups I-VI, XII, XIII, XXII, XXIII, XXVIII) can be used in a materially different method of using from each of the different methods (Groups VII, VIII, X-XII, XVI, XVIII, XIX-XXI, XXIV-XXVIII). For example, each of the recited products can be used as a therapeutic agent for treatment of diseases associated with altered expression of nuclear proteins which bind to a transcriptional regulatory DNA element of a target gene (such as an immunoglobulin gene).

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
March 20, 2006

DAVID GUZO
PRIMARY EXAMINER